

**IVERMAX PLUS- ivermectin and clorsulon injection**  
**Aspen Veterinary Resources**

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**Approved by FDA under ANADA # 200-450**

**Restricted Drug (California) -Use Only as Directed.**

**IVERMAX® PLUS**

**(ivermectin and clorsulon)**

**Injection for Cattle**

**For the effective treatment and control of internal parasites, including adult liver flukes, and external parasites.**

**Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.**

**INTRODUCTION**

The ability of ivermectin to deliver internal and external parasite control has been proven in cattle markets around the world. Now, Ivermax® Plus combines ivermectin, the active ingredient of Ivermax® 1%, with clorsulon, an effective adult flukicide. A single injection of Ivermax® Plus (ivermectin and clorsulon) offers all the benefits of Ivermax® 1% plus control of adult *Fasciola hepatica*.

**The dosage level of clorsulon supplied by Ivermax® Plus is effective only against adult liver flukes (*Fasciola hepatica*).**

**PRODUCT DESCRIPTION**

Ivermax® Plus is a ready-to-use sterile solution containing 1% w/v ivermectin, 10% w/v clorsulon, 40% glycerol formal, and propylene glycol, q.s. ad 100%. It is formulated to deliver the recommended dose level of 200 mcg ivermectin/kg and 2 mg clorsulon/kg given subcutaneously behind the shoulder at the rate of 1 ml per 110 lb (50 kg) body weight.

**MODE OF ACTION**

Ivermectin is a member of the macrocyclic lactone class of endectocides which have a unique mode of action. Compounds of the class bind selectively and with high affinity to glutamate-gated chloride ion channels which occur in invertebrate nerve and muscle cells. This leads to an increase in the permeability of the cell membrane to chloride ions with hyperpolarization of the nerve or muscle cell, resulting in paralysis and death of the parasite. Compounds of this class may also interact with other ligand-gated chloride channels, such as those gated by the neurotransmitter gamma-aminobutyric acid (GABA).

The margin of safety for compounds of this class is attributable to the fact that mammals do not have glutamate-gated chloride channels, the macrocyclic lactones have a low affinity for other mammalian ligand-gated chloride channels and they do not readily cross the blood-brain barrier. Clorsulon is rapidly absorbed into the circulating blood. Erythrocytes with bound drug as well as plasma are ingested by *Fasciola hepatica*. Adult *Fasciola hepatica* are killed by clorsulon because of inhibition of enzymes in the glycolytic pathway, which is their primary source of energy.

**INDICATIONS**

Ivermax® Plus is indicated for the effective treatment and control of the following parasites in cattle:

**Gastrointestinal Roundworms** (adults and fourth-stage larvae):

*Ostertagia ostertagi* (including inhibited *O. ostertagi*)

*O. lyrata*

*Haemonchus placei*

*Trichostrongylus axei*

*T. colubriformis*

*Cooperia oncophora*

*C. punctata*

*C. pectinata*

*Bunostomum phlebotomum*

*Nematodirus helvetianus* (adults only)

*N. spathiger* (adults only)

*Oesophagostomum radiatum*

**Lungworms** (adults and fourth-stage larvae):

*Dictyocaulus viviparus*

**Liver Flukes:**

*Fasciola hepatica* (adults only)

**Cattle Grubs** (parasitic stages):

*Hypoderma bovis*

*H. lineatum*

**Sucking Lice:**

*Linognathus vituli*

*Haematopinus eurysternus*

*Solenopotes capillatus*

**Mange Mites** (Cattle Scab\*):

*Psoroptes ovis* (syn. *P. communis* var. *bovis*)

*Sarcoptes scabiei* var. *bovis*

**Persistent Activity**

Ivermectin and clorsulon injection has been proved to effectively control infections and to protect cattle from reinfection with *Dictyocaulus viviparus* and *Oesophagostomum radiatum* for 28 days after treatment; *Ostertagia ostertagi*, *Trichostrongylus axei* and *Cooperia punctata* for 21 days after treatment; *Haemonchus placei* and *Cooperia oncophora* for 14 days after treatment.

\*Ivermectin has been approved as a scabicide by USDA/APHIS. Federal regulations require that cattle infested with or exposed to scabies (i.e., infestations with *Psoroptes ovis*) be treated. Ivermectin when used according to label instructions meets this requirement. Treated cattle may be shipped interstate, but they must not be mixed with other cattle for 14 days following treatment. The federal regulations make no restriction on the movement of cattle not affected with or exposed to scabies. However, individual states have additional regulations to govern the interstate shipment of cattle and the regulatory veterinarian in the state of destination should be consulted for applicable regulations on the use of ivermectin in the control of scabies.

## DOSAGE

Ivermax® Plus should be given only by subcutaneous injection at a dose volume of 1 ml per 110 lb. (50 kg) body weight. This volume will deliver 10 mg ivermectin and 100 mg clorsulon. For example:

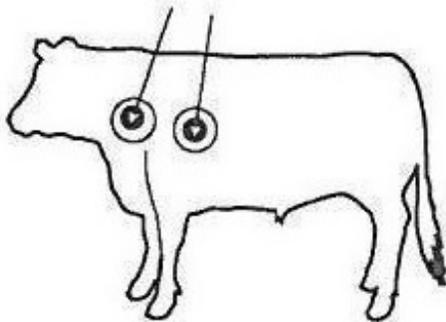
Body Weight (lb)	Dose Volume (mL)
220	2
330	3

440	4
550	5
660	6
770	7
880	8
990	9
1100	10

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## ADMINISTRATION

Ivermax® Plus (ivermectin and clorsulon) is to be given subcutaneously only. Animals should be appropriately restrained to achieve the proper route of administration. Use of a 16-gauge, ½” to ¾” sterile needle is recommended. Inject the solution subcutaneously (under the skin) behind the shoulder (see illustration).



When using the 500 ml or 1000 ml package size, use only automatic syringe equipment.

Use sterile equipment and sanitize the injection site by applying a suitable disinfectant. Clean, properly disinfected needles should be used to reduce the potential for injection site infections.

No special handling or protective clothing is necessary.

The viscosity of the product increases in cool temperatures. Administering Ivermax® Plus at temperatures of 5°C (41°F) or below may be difficult. Users can make dosing easier by warming both the product and injection equipment to about 15°C (59°F).

Use within 28 days of first puncture and puncture a maximum of 14 times with a dosage delivery device.

## ANIMAL SAFETY

In breeding animals (bulls and cows), ivermectin and clorsulon used at the recommended level had no effect on breeding performance.

### **WARNING: NOT FOR USE IN HUMANS.**

**Keep this and all drugs out of reach of children.**

The Safety Data Sheet (SDS) contains more detailed occupational safety information. To report adverse effects, obtain an SDS or for assistance, contact Bimeda, Inc. at 1-888-524-6332.

**RESIDUE WARNING:** Do not treat cattle within 21 days of slaughter. Because a withdrawal period in milk has not been established, do not use in female dairy cattle of breeding age. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

## PRECAUTIONS

Transitory discomfort has been observed in some cattle following subcutaneous administration. Soft tissue swelling at the injection site has also been observed. These reactions have disappeared without treatment. Divide doses greater than 10 mL between two

injection sites to reduce occasional discomfort or site reaction. Different injection sites should be used for other parenteral products.

Ivermax® Plus has been developed specifically for use in cattle only. This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result.

For subcutaneous injection in cattle only. This product is not for intravenous or intramuscular use.

Restricted Drug (California)-Use Only as Directed.

### **When to Treat Cattle with Grubs**

Ivermax® Plus effectively controls all stages of cattle grubs. However, proper timing of treatment is important. For most effective results, cattle should be treated as soon as possible after the end of the heel fly (warble fly) season.

Destruction of *Hypoderma larvae* (cattle grubs) at the period when these grubs are in vital areas may cause undesirable host-parasite reactions including the possibility of fatalities. Killing *Hypoderma lineatum* when it is in the tissue surrounding the esophagus (gullet) may cause bloat; killing *H. bovis* when it is in the vertebral canal may cause staggering or paralysis. These reactions are not specific to treatment with Ivermax® Plus, but can occur with any successful treatment of grubs. Cattle should be treated either before or after stages of grub development. Consult your veterinarian concerning the proper time for treatment.

Cattle treated with Ivermax® Plus after the end of the heel fly season may be retreated with ivermectin during the winter for internal parasites, mange mites, or sucking lice, without danger of grub-related reactions. A planned parasite control program is recommended.

Protect product from light.

### **Environmental Safety**

Studies indicate that when ivermectin comes in contact with soil, it readily and tightly binds to the soil and becomes inactive over time. Free ivermectin may adversely affect fish and certain aquatic organisms. Do not permit water runoff from feedlots to enter lakes, streams or ponds. Do not contaminate water by direct application or by improper disposal of drug containers. Dispose of containers in an approved landfill or by incineration.

As with other avermectins, ivermectin is excreted in the dung of treated animals and can inhibit the reproduction and growth of pest and beneficial insects that use dung as a source of food and for reproduction. The magnitude and duration of such effects are species and life-cycle specific. When used according to label directions, the product is not expected to have an adverse impact on populations of dung-dependent insects.

### **HOW SUPPLIED**

Ivermax® Plus is available in two ready-to-use sizes:

The 500 mL plastic bottle is suitable for use with automatic syringe equipment. Each bottle contains sufficient solution to treat 100 head of 550 lb (250 kg) cattle.

The 1000 mL plastic bottle is suitable for use with automatic syringe equipment. Each bottle contains sufficient solution to treat 200 head of 550 lb (250 kg) cattle.

Store at 20°C to 25°C (68°F to 77°F). Protect from light.



Ivermax<sup>®</sup> Plus (ivermectin and clorsulon) combines ivermectin for internal and external parasite control and clorsulon, which effectively controls adult liver flukes.

1% w/v ivermectin and 10% w/v clorsulon in a sterile solution

**WARNING: NOT FOR USE IN HUMANS.**  
Keep this and all drugs out of the reach of children.

**RESIDUE WARNING:** Do not treat cattle within 21 days of slaughter. Because a withdrawal period in milk has not been established, do not use in female dairy cattle of breeding age. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

**PRECAUTIONS**

Use automatic syringe equipment only.

For subcutaneous injection in cattle only. This product is not for intravenous or intramuscular use.

Protect product from light.

Restricted Drug (California) - Use Only as Directed.

Ivermax<sup>®</sup> Plus (ivermectin and clorsulon) Injection for Cattle has been developed specifically for use in cattle **only**. This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result.

Do not contaminate water by direct application or by improper disposal of drug containers. Dispose of containers in an approved landfill or by incineration.

**ANIMAL SAFETY**

In breeding animals (bulls and cows), ivermectin and clorsulon used at the recommended level had no effect on breeding performance.

Store at 20° C to 25° C (68° F to 77° F).

Use within 28 days of first puncture and puncture a maximum of 14 times with a dosage delivery device.

**Manufactured for:**

Aspen Veterinary Resources, Ltd.  
Liberty, MO 64068, USA  
www.aspenveterinaryresources.com  
A200B 01/19



**IVERMAX<sup>®</sup> PLUS**  
(ivermectin and clorsulon)  
Injection for Cattle

NDC # 46066-100-05



**IVERMAX<sup>®</sup> PLUS**  
(ivermectin and clorsulon)  
Injection for Cattle



**Treats 100-550 lb Cattle**  
**For the treatment and control of internal**  
**parasites, including adult liver flukes, and**  
**external parasites.**

Approved by FDA under ANADA # 200-450

**NET CONTENTS:**  
**500 mL**



Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

**INDICATIONS**

Ivermax® Plus (ivermectin and clorisulon) is indicated for the treatment and control of gastrointestinal roundworms (including inhibited *Ostertagia ostertagi* larvae), lungworms, adult liver flukes, grubs (note insert precautions), sucking lice, and mange mites (cattle scab (note insert indications)). See package insert for complete indications and use directions.

The dosage level of clorsulon supplied by Ivermax® Plus is effective only against adult liver flukes (*Fasciola hepatica*).

**RECOMMENDED DOSE**

Ivermax® Plus should be given only by subcutaneous injection at a dose volume of 1 mL per 110 lb (50 kg) body weight. This volume will deliver 10 mg ivermectin and 100 mg clorsulon.

This bottle is designed for use with automatic syringe equipment only.

It contains enough solution to treat one hundred 550 lb cattle.

For example:

Body Weight (lb)	Dose (mL)	Doses per Pack
220	2	250
330	3	166
440	4	125
550	5	100
660	6	83
770	7	71
880	8	62
990	9	56
1100	10	50

For body weights over 1100 lbs., administer at 1 mL per 110 lbs. (50 kg). Divide doses greater than 10 mL between two injection sites to reduce occasional transitory discomfort or site reaction.

Product No. 11VE044  
81VE048  
Rev. 01/19

NDC # 46066-100-05



# IVERMAX® PLUS

(ivermectin and clorsulon)  
Injection for Cattle



**Treats 100-550 lb Cattle**  
For the treatment and control of internal parasites, including adult liver flukes, and external parasites.

Approved by FDA under ANADA # 200-450

**NET CONTENTS:**  
500 mL

**WARNING: NOT FOR USE IN HUMANS.**  
Keep this and all drugs out of the reach of children.

**RESIDUE WARNING:** Do not treat cattle within 21 days of slaughter. Because a withdrawal period in milk has not been established, do not use in female dairy cattle of breeding age. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

**PRECAUTIONS**

Use automatic syringe equipment only. For subcutaneous injection in cattle only. Protect product from light.

Restricted Drug (California) - Use Only as Directed.

\* Ivermax is a registered trademark of Aspen Veterinary Resources,™ Ltd.  
Product No. 11VE044 81VE047 Rev. 01/19

NDC # 46066-100-05



# IVERMAX® PLUS

(ivermectin and clorsulon)  
Injection for Cattle



Approved by FDA under ANADA # 200-450

**NET CONTENTS:**  
500 mL

For the treatment and control of internal parasites, including adult liver flukes, and external parasites.

Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

Do not contaminate water. Dispose of containers in an approved landfill or by incineration.

See package insert for complete indications, precautions, warnings, residue information, and use directions.

Store at 20° C to 25° C (68° F to 77° F).

Use within 28 days of first puncture and puncture a maximum of 14 times with a dosage delivery device.



Manufactured for:  
Aspen Veterinary Resources,™ Ltd.  
Liberty, MO 64068, USA  
www.aspenveterinaryresources.com  
A2008 01/19



**IVERMAX PLUS**

ivermectin and clorsulon injection

### Product Information

<b>Product Type</b>	OTC ANIMAL DRUG	<b>Item Code (Source)</b>	NDC:46066-100
<b>Route of Administration</b>	SUBCUTANEOUS		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
IVERMECTIN (UNII: 8883YP2R6D) (IVERMECTIN - UNII:8883YP2R6D)	IVERMECTIN	10 mg in 1 mL
CLORSULON (UNII: EG1ZDO6LRD) (CLORSULON - UNII:EG1ZDO6LRD)	CLORSULON	100 mg in 1 mL

### Packaging

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:46066-100-05	500 mL in 1 VIAL, MULTI-DOSE		
2	NDC:46066-100-06	1000 mL in 1 VIAL, MULTI-DOSE		

### Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANADA	ANADA200450	06/06/2019	

**Labeler** - Aspen Veterinary Resources (627265361)

**Registrant** - Bimeda, Inc. (060492923)

### Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Bimeda-MTC		256232216	manufacture

### Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Aino Co., Ltd. of North China Pharmaceutical Group		529804676	api manufacture

### Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Alivira Animal Health Limited		650916617	api manufacture

### Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Shandong Qilu King-phar Pharmaceutical Co., Ltd.		421524323	api manufacture